Biological (Tissue) Valve in a 60 year old patient: Debate

Tissue vs Mechanical
What’s the Data??

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Surgical Director, Heart and Vascular Center
Director, Thoracic Aortic Surgery Program
General Trends in the Nation
Isolated aortic valve replacement in North America comprising 108,687 patients in 10 years: Changes in risks, valve types, and outcomes in the Society of Thoracic Surgeons National Database
National trends in utilization and in-hospital outcomes of mechanical versus bioprosthetic aortic valve replacements

Abby J. Isaacs, MS, Jeffrey Shuhaiber, MD, Arash Salemi, MD, O. Wayne Isom, MD, and Art Sedrakyan, MD, PhD

The Journal of Thoracic and Cardiovascular Surgery • May 2015

National Use Snapshot

• Use of Bioprosthetic Valves has increased by >70% in 14 years particularly for patients 55-64
  • National Inpatient sample: Issacs, et al; JTCVS 2015
  • 64% of Valves in 2011 were Bioprosthetic
  • Important: Despite Bioprosthetic Valves having:
    • Higher CHF rates, Higher diabetes, higher COPD, and higher CRI
    • There was LOWER mortality = 4.4% vs 4.9% and propensity adjusted was 4.4% vs 5.2% (P<.001)
    • Bioprosthetic Valves were preferentially used in Mid-High Volume centers

• Thomboembolism and Bleeding account 75% of all complications after mechanical Valves (Kulik, et al Ann Thor Surg 2006)
Early Data Regarding the Concept
Mechanical Valves have higher Acute mortality
From STS Guidelines


Fig 3. Survival by age groups: (A) younger patients; (B) middle-aged patients; (C) elderly patients. Note that differences disappear.

Not Much difference
Recent Data on a 60 year old??
Original Investigation

Survival and Long-term Outcomes Following Bioprosthetic vs Mechanical Aortic Valve Replacement in Patients Aged 50 to 69 Years

Yuting P. Chiang, BA; Joanna Chikwe, MD; Alan J. Moskowitz, MD; Shinobu Itagaki, MD; David H. Adams, MD; Natalia N. Egorova, PhD

JAMA October 1, 2014 Volume 312, Number 13
Short Term Outcomes: The Same

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Bioprosthetic (n = 1001)</th>
<th>Mechanical (n = 1001)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>25 (3)</td>
<td>30 (3)</td>
<td>.49</td>
</tr>
<tr>
<td>Stroke</td>
<td>18 (2)</td>
<td>12 (1)</td>
<td>.26</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>129 (12)</td>
<td>135 (13)</td>
<td>.69</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>18 (2)</td>
<td>16 (2)</td>
<td>.73</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>101 (10)</td>
<td>86 (9)</td>
<td>.26</td>
</tr>
<tr>
<td>Readmission</td>
<td>173 (17)</td>
<td>172 (17)</td>
<td>.95</td>
</tr>
</tbody>
</table>
Survival and Long-term Outcomes Following Bioprosthetic vs Mechanical Aortic Valve Replacement in Patients Aged 50 to 69 Years

Yuting P. Chiang, BA; Joanna Chikwe, MD; Alan J. Moskowitz, MD; Shinobu Itagaki, MD; David H. Adams, MD; Natalia N. Egorova, PhD

Figure 1. Overall Survival Among Propensity-Matched Patients Aged 50 to 69 Years After Bioprosthetic vs Mechanical Aortic Valve Replacement

No Difference in Outcomes
NY State Database 1997-2004
Analyzed to 2014
Propensity matched
Median follow up = 11 years

50-69 years old
Complications: Stroke the same; Reoperation higher in Bioprosthetic; Bleeding higher in Mechanical

Figure 2. Cumulative Incidence of Major Morbidity (Stroke, Reoperation, Major Bleeding) Among Propensity-Matched Patients Aged 50 to 69 Years After Bioprosthetic vs Mechanical Aortic Valve Replacement

- **Stroke**
  - HR, 1.04 (95% CI, 0.75-1.43); Gray P = .84

- **Reoperation**
  - HR, 0.52 (95% CI, 0.36-0.75); Gray P = .001

- **Major bleeding**
  - HR, 1.75 (95% CI, 1.27-2.43); Gray P = .001

<table>
<thead>
<tr>
<th>No. at risk</th>
<th>Years</th>
<th>Bioprosthetic</th>
<th>Mechanical</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>15</td>
<td>836</td>
<td>466</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>1001</td>
<td>43</td>
</tr>
<tr>
<td>0</td>
<td>10</td>
<td>827</td>
<td>480</td>
</tr>
<tr>
<td>0</td>
<td>15</td>
<td>1001</td>
<td>48</td>
</tr>
</tbody>
</table>

There were 68 strokes in the bioprosthesis group vs 71 in the mechanical prosthesis group; 79 reoperations in the bioprosthesis group vs 43 in the mechanical prosthesis group; and 58 major bleeding events in the bioprosthesis group vs 101 in the mechanical prosthesis group.
Bioprostheses in Patients <65

Figure 2: Cumulative survival and reoperation-free survival after bioprosthetic AVR.

N=84, no SVD above age 56

Bioprosthetic AVR, age <60 (416, 1977-2013), Freedom from SVD

Reasonable outcomes with Tissue Valves in age 50-60

Bioprosthetic AVR, age <60 (416, 1977-2013), Freedom from SVD, survival, reoperation for SVD


Interesting data:
Survival for 50-60 BETTER than 40-50!!

Not sure this should go below 50??
Kaplan–Meier estimates of freedom from SVD by age group. Age was not a significant risk factor among this age subgroup.

• Kaplan–Meier estimates of freedom from reoperation due to structural valve deterioration (SVD) by age group. Age was not a significant risk factor among this age subgroup.

Comparison of expected valve durability, life expectancy after AVR and relative life expectancy of the general population in France. The cohort was sub-divided by decile of age (10 groups—mean age on the X-axis). AVR reduces life expectancy compared with the general population, although the difference declines with age at surgery. In most of the age groups, the expected valve durability estimate is similar to or slightly higher than the life expectancy after AVR.

After age 54, The Durability of the Valve is longer than Life Expectancy

Life expectancy edge by age of implant

Figure 1  Mean difference (95% confidence limits) in life expectancy between bioprostheses and mechanical valves by age. Values above 0 favour bioprostheses. CABG, coronary artery bypass grafting.

The Myth of Superior Hemodynamics in Mechanical Valves

Results from Recent FDA Trials
The St Jude Medical Trifecta aortic pericardial valve: Results from a global, multicenter, prospective clinical study

Joseph E. Bavaria, MD, a Nimesh D. Desai, MD, PhD, a Anson Cheung, MD, b Michael R. Petracek, MD, c Mark A. Groh, MD, d Michael A. Borger, MD, e and Hartzell V. Schaff, MD f

**FIGURE 7.** Average mean valve gradients over time.
The St Jude Medical Trifecta aortic pericardial valve: Results from a global, multicenter, prospective clinical study

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**FIGURE 10.** Average EOAi. EOAi, Effective orifice area index.
The COMMENCE trial: 2-year outcomes with an aortic bioprosthesis with RESILIA tissue†


- Mean Gradients at 2 years:
  - 16 mmHg for 19 mm; 11 mmHg for 21 mm, 10 mmHg for 23 mm
  - 9 mmHg for 25 mm; 8 mmHg for 27mm, and 5 mmHg for 29mm

- Simply Excellent!

- EJTCVS 2017
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**FIGURE 11.** Total aortic insufficiency over time.
(or TAVR) in this 60 year old?
Paravalvular Leak: S3HR & S3i (Valve Implant Patients)

- **0.1%** in S3HR
- **3.7%** in S3i
- **4.2%** in overall

Lots of Residual AI: Even with 3rd generation S3
### Clinical Performance Evolute CE Mark

<table>
<thead>
<tr>
<th>Event, %</th>
<th>N=60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absence of procedural mortality</td>
<td>100.0 (60/60)</td>
</tr>
<tr>
<td>Correct positioning of 1 valve in proper location</td>
<td>98.3 (59/60)</td>
</tr>
<tr>
<td>Mean gradient &lt; 20 mm Hg or peak velocity &lt; 3m/sec</td>
<td>98.3 (59/60)</td>
</tr>
<tr>
<td>Absence of moderate or severe regurgitation</td>
<td>93.3 (56/60)</td>
</tr>
<tr>
<td>Absence of patient prosthesis mismatch*</td>
<td>83.6 (46/55)</td>
</tr>
<tr>
<td>VARC-2 device success†</td>
<td>78.6 (44/56)</td>
</tr>
</tbody>
</table>

*Effective orifice area could not be determined in 5 patients to calculate patient prosthesis mismatch.

†First time reporting of device success according to VARC-2 criteria

## Secondary Endpoints

<table>
<thead>
<tr>
<th>Events*</th>
<th>1 Month</th>
<th>1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Stroke, %</td>
<td>4.0</td>
<td>7.0</td>
</tr>
<tr>
<td>Major, %</td>
<td>2.3</td>
<td>4.3</td>
</tr>
<tr>
<td>Myocardial Infarction, %</td>
<td>1.2</td>
<td>2.0</td>
</tr>
<tr>
<td>Reintervention, %</td>
<td>1.1</td>
<td>1.8</td>
</tr>
<tr>
<td>VARC Bleeding, %</td>
<td>36.7</td>
<td>42.8</td>
</tr>
<tr>
<td>Life Threatening or Disabling, %</td>
<td>12.7</td>
<td>17.6</td>
</tr>
<tr>
<td>Major, %</td>
<td>24.9</td>
<td>28.5</td>
</tr>
<tr>
<td>Major Vascular Complications, %</td>
<td>8.2</td>
<td>8.4</td>
</tr>
<tr>
<td><strong>Permanent Pacemaker Implant, %</strong></td>
<td>21.6</td>
<td>26.2</td>
</tr>
<tr>
<td>Per ACC Guidelines, %</td>
<td>17.1</td>
<td>19.2</td>
</tr>
</tbody>
</table>

* Percentages obtained from Kaplan Meier estimates

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**TCT 2013 LBCT (JACC 2014)**

**Extreme Risk Study | Iliofemoral Pivotal**
<table>
<thead>
<tr>
<th>Events (%)</th>
<th>S3HR Overall (n=583)</th>
<th>S3HR TF (n=491)</th>
<th>S3HR TA/TA (n=92)</th>
<th>S3i Overall (n=1076)</th>
<th>S3i TF (n=951)</th>
<th>S3i TA/TA (n=125)</th>
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</thead>
<tbody>
<tr>
<td>Major Vascular Comps.</td>
<td>5.0</td>
<td>5.3</td>
<td>3.3</td>
<td>5.6</td>
<td>5.9</td>
<td>3.2</td>
</tr>
<tr>
<td>Bleeding - Life Threatening</td>
<td>6.3</td>
<td>5.5</td>
<td>10.9</td>
<td>5.4</td>
<td>4.4</td>
<td>12.9</td>
</tr>
<tr>
<td>Annular Rupture</td>
<td>0.3</td>
<td>0.2</td>
<td>1.1</td>
<td>0.2</td>
<td>0.2</td>
<td>0</td>
</tr>
<tr>
<td>Myocardial Infarctions</td>
<td>0.5</td>
<td>0.4</td>
<td>1.1</td>
<td>0.3</td>
<td>0.3</td>
<td>0</td>
</tr>
<tr>
<td>Coronary Obstruction</td>
<td>0.2</td>
<td>0</td>
<td>1.1</td>
<td>0.4</td>
<td>0.4</td>
<td>0</td>
</tr>
<tr>
<td>Acute Kidney Injury</td>
<td>1.0</td>
<td>0.8</td>
<td>2.2</td>
<td>0.5</td>
<td>0.3</td>
<td>1.6</td>
</tr>
<tr>
<td>New Permanent Pacemaker</td>
<td>13.0</td>
<td>13.2</td>
<td>12.0</td>
<td>10.1</td>
<td>10.4</td>
<td>7.2</td>
</tr>
<tr>
<td>Aortic Valve Re-intervention</td>
<td>1.0</td>
<td>0.8</td>
<td>2.2</td>
<td>0.7</td>
<td>0.8</td>
<td>0</td>
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<tr>
<td>Endocarditis</td>
<td>0.2</td>
<td>0.2</td>
<td>0</td>
<td>0.1</td>
<td>0.1</td>
<td>0</td>
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TAVR: Catastrophic Procedure Details

Source: STS/ACC TVT Registry Database.
80,130 records as of Jan 18, 2017
Guidelines
Guideline Cutoffs

Figure 2  Guideline recommendations for the use of mechanical and bioprosthesis prostheses for aortic valve replacement. Recommendations from the North American AHA/ACC and European ESC/EACTS guidelines.  

Figure: Head SJ, Celik M, Kappetein AP. Mechanical versus bioprosthetic aortic valve replacement. Eur Heart J. 2017;38(28):2183-2191.
Factors that could influence changes in cutoff @ 60

**Figure 4** Advancements in therapy related to mechanical and bioprosthetic valves that may change the cut-off for implanting a bioprosthesis. Adapted from Head and co-authors.\(^\text{10}\) AVR, aortic valve replacement; INR, international normalized ratio; TAVI, transcatheter aortic valve implantation.

60 year old who needs an Aortic Valve??
(What would I want for Myself ... 59)

Surgically Placed NEW Tissue Aortic Valves

Great hemodynamics, Longer Durability, Incredibly low mortality, and basically zero AI and close to zero pacemakers!!!